K100532

510(k) SUMMARY

Versalok Peek Anchor

Submitter's Name and Address:	DePuy Mitek, Inc. a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 MAR 17 2010
Contact Person	Kristine Christo Regulatory Affairs Project Manager DePuy Mitek, Inc. a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 Telephone: 508-828-3359 Facsimile: 508-977-6911 e-mail: kchristo@its.jnj.com Prepared: 2/24/10
Name of Medical Device	Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners Common/Usual Name: Bone Anchor Proprietary Name: Versalok Peek Anchor
Substantial Equivalence	Versalok Peek Anchor is substantially equivalent to: Trident Anchor (K060914) Versalok Ti Anchor (K063478) Arthrex Pushlock Anchor (K063479)
Device Classification	This device carries an FDA product code MBI and HWC, and is classified as Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners under 21 CFR 888.3040.
Device Description	The Versalok Peek Anchor System includes the Versalok Peek Anchor, which will be presented sterile, pre-mounted on an inserter shaft w/anvil

	with a threader tab and suture. The System will be deployed with the use of a reusable Deployment Gun. The system is provided with and without a Orthocord#2 suture. The VERSALOK Anchor System offers several additional clinical benefits as the anchor allows the surgeon to fix the tissue without tying knots and the delivery system allows the surgeon to control the tension placed on the tissue with the tension wheel of the deployment gun. Technologies characteristics including material, design, packaging and indications are the same as the predicate cleared devices and use similar or identical material and packaging as the predicates.
Indications for Use	The Versalok Peek Anchor is indicated for use in the following: **Shoulder:** Rotator Cuff Repair, Biceps Tenodesis, **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; Joint Capsule Closure **Elbow:** Biceps Tendon Reattachment
Nonclinical testing:	Verification activities were performed on the implant or its predicates. Testing includes pull out testing, shelf life, sterilization and biocompatibility.
Safety and Performance	Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Versalok Peek Anchor has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.
Predicate Comparison	The proposed Versalok Peek Anchor is compared to the predicate Trident Anchor (K063478), Versalok Anchor (K060914) and Arthrex Pushlock (K063479) below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek
% Ms. Kristine Christo
Regulatory Affairs Project Manager
325 Paramount Drive
Raynham, Massachusetts 02767

MAR 17 2010

Re: K100532
Trade/Device Name: VERSALOCK Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MBI
Dated: February 24, 2010
Received: February 25, 2010

Dear Ms. Christo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100532

Device Name:

VERSALOCK Anchor is indicated for use in the following:

Shoulder: Rotor Cuff Repair, Biceps Tenodesis
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; Joint Capsule Closure
Elbow: Biceps Tendon Reattachment

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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